

EXHIBIT 194

From: Millward, Joseph
Sent: Thu, 18 Aug 2011 12:43:30 -0400
To: STR_Pharmacy_PDLS
Cc: Chunderlik, George;Springer, Nancy;Kakiou, Christina
Subject: FW: Controlled drug procedures
Attachments: DEA Fax Notification form.doc, Diversion Prevention Procedures.doc, Filling Controlled Prescriptions.docx, Ohio Loss Fax form.doc, Drug Loss-Close Process Checklist.xlsx, GIANT EAGLE CONTROLLED SUBSTANCE LOSS PROCEDURE (2) (2).doc, Receiving Controlled Drugs.docx

Team,

Attached are the documents that were presented this morning. Please review the documents and provide feedback.



Thanks,

Joseph E. Millward, RPh
Senior Manager, Pharmacy Quality and Compliance
Giant Eagle, Inc.
o: 412-963-5952
c: 412-316-6266
f: 412-968-1552

GIANT EAGLE PHARMACY
Suspected Controlled Substance Loss
DEA Notification: PA, MD, and WV

Date: _____

Dear Agent in Charge:

The Giant Eagle pharmacy listed below has identified a suspected controlled drug loss. If we confirm the suspected loss as actual, we will initiate a loss prevention investigation and notify the local police department and state regulatory agency. We will submit a DEA-106 once we have gathered adequate information about the actual loss. If you have any questions concerning this suspected loss or the outcome of the preliminary audit, or if you would like to assist in the investigation, please contact the Pharmacy District Leader listed below.

Details and Date of Suspected Loss:

Giant Eagle Pharmacy #: _____

Pharmacy Address: _____

Telephone: _____

DEA Number: _____

Pharmacy District Leader: _____

Address: _____

Office Telephone: _____

Cell Phone: _____

Pharmacy Instructions:

Please check one of the boxes below to indicate which office was notified:

DEA Offices Covering Giant Eagle Pharmacies:

DEA Office	Area/State Covered	Phone Number	Fax Number
<input type="checkbox"/> Pittsburgh Resident Office	Western PA (Zip Codes 150 to 168)	412-777-1870	412-777-1880
<input type="checkbox"/> Baltimore District Office	Maryland	410-244-3629	410-244-3590
<input type="checkbox"/> Charleston Resident Office	West Virginia	304-347-5209	304 347-5212

The pharmacy must fax this form to the following at Giant Eagle, Inc.:

Sr. Manager of Quality and Compliance at 412-968-1552

Sr. Director Risk Management Services and Corporate Counsel at 412-967-3761

Form Date: 07-28-11

	<h1>Diversion Prevention Procedures</h1>	Compliance
Steps:		
<ol style="list-style-type: none"> 1. Store all personal items in a secure, designated area in the store – no personal items are permitted in the pharmacy including cell phones. 2. Remove smocks and leave them in the pharmacy during breaks. 		
<p style="background-color: #cccccc; padding: 5px;">NOTE: Smock checks, bag checks will be instituted when necessary.</p>		
<ol style="list-style-type: none"> 3. Limit access to the pharmacy by only allowing people to enter the pharmacy when a pharmacist is on duty and only allowing approved people to enter the pharmacy including: <ul style="list-style-type: none"> • On-duty team members • Giant Eagle store leadership • Giant Eagle visiting leadership • Law enforcement officials* • State Board of Pharmacy inspectors* • Maintenance or repair persons* • Third party auditors* 		
<p style="background-color: #cccccc; padding: 5px;">NOTE: People identified with and asterisks (*) must show proper identification or credentials before being permitted into the pharmacy.</p>		
<ol style="list-style-type: none"> 4. Limit access to the pharmacy by not allowing unapproved people to enter the pharmacy including: <ul style="list-style-type: none"> • Salespeople and manufacturer's representatives • Customers • Family • Friends • Pharmacy supplier delivery drivers • Off-duty team members (other than salaried registered pharmacists) 5. Secure the pharmacy with gates and/or door locks and activated alarms when the pharmacy is closed and the pharmacist is not present in the building. 6. Avoid pharmacists filling prescriptions for themselves or family members <ul style="list-style-type: none"> • Another pharmacist on duty must fill the prescription • If there is no other pharmacist on duty, a member of store leadership must witness the filling and dispensing of the prescription and initial both the hardcopy of the prescription and the signature log. <p style="background-color: #cccccc; padding: 5px;">NOTE: Pharmacy laws do not prohibit pharmacists from filling prescriptions for themselves or family members, but Giant Eagle preferred practices requires pharmacists to only fill for themselves or family members if no other pharmacist is on duty.</p> <ol style="list-style-type: none"> 7. Comply with the Giant Eagle Associate Purchase Policy. <ul style="list-style-type: none"> • Associates may not ring up their own purchases or purchases of their family members including both prescription and non-prescription purchases. 		

	<h1>Filling Controlled Prescriptions</h1>	Compliance
Steps:		
CII Prescriptions		
<ol style="list-style-type: none">1. Double count each prescription.<ul style="list-style-type: none">• Two different pharmacy team members must count each CII prescription• A pharmacist must be the final pharmacy team member to count each CII prescription2. Place two Xs (XX) and the pharmacist's initials that completed the second count in the upper right hand corner of the prescription label.3. Enter the prescription information in the CII perpetual inventory logbook.4. Return the stock bottles to the locked cabinet or safe immediately after completing the final verification.		
CIII – V Prescriptions		
<ol style="list-style-type: none">1. Double count each prescription.<ul style="list-style-type: none">• The same team member may count both counts.2. Place two Xs (XX) and the team member initials that completed the second count in the upper right hand corner of the prescription label.		

**Giant Eagle Pharmacy
Suspected Drug Loss
Ohio Notification Form**

Date: _____

Dear Agent in Charge:

The Giant Eagle pharmacy listed below has identified a suspected drug loss. In order to be fully compliant with Ohio Board of Pharmacy rule **4729-9-15**, we are using this form to notify you in writing of the suspected loss. We will fully comply with the board of pharmacy agent's and law enforcement's investigation.

Details and Date of Suspected Loss:

Giant Eagle Pharmacy #: _____

Pharmacy Address: _____

Telephone: _____

DEA Number: _____

Pharmacy District Leader: _____

Address: _____

Office Telephone: _____

Cell Phone: _____

Pharmacy Instructions:

Check to confirm notification:

Ohio Board of Pharmacy **Phone: 614-466-4143** **Fax: 614-752-4836**

Local law enforcement: **Fax:**

Drug Enforcement Agency Resident Offices (please check one of the boxes below):

**DEA CLEVELAND RESIDENT
OFFICE**

Courthouse Square
1375 East 9th Street Suite 700
Cleveland, OH 44114
Diversion Number: (216) 274-3600
Diversion Fax: (216) 664-1307
Jurisdiction: Northern Ohio

**DEA COLUMBUS RESIDENT
OFFICE**

500 South Front Street, Suite 612
Columbus, OH 43215
Diversion Number: (614) 255-4200
Diversion Fax: (614) 469-5788
Jurisdiction: Central and Southern Ohio

Detroit Division

211 W. Fort Street, Suite 610
Detroit, MI 48226
Diversion Number: (313) 834-4000
Diversion Fax: (313) 225-2163
Jurisdiction: Toledo

Please fax this form to the following at Giant Eagle, Inc.:
Sr. Manager of Quality and Compliance at 412-968-1552
Sr. Director Risk Management Services and Corporate Counsel at 412-967-3761

Form Date: 02-11-11 Revised 08-09-11

This is a generated placeholder for a document that matches the selected file type(s).

Location: Quality\Policy\Controlled Drug Receiving, Compliance, and Reporting\FW_ Controlled drug procedures

Title: Drug Loss-Close Process Checklist

Doc Type: Microsoft Excel XML Workbook

Date: 18 Aug 2011 12:43:30

Est. Date: No

Description:

Notes:

Lost/Theft/Missing Controlled Substance Process Checklist

Pharmacy Leader:

Giant Eagle Pharmacy #

Date:

Pharmacy District Leader:

REASON FOR LOSS:

Loss Process Checklist					
Activity	Activity Owner	Completed by (initials)	Status	Date Completed	Notes
Loss notification: internal					
Pharmacy District Leader (PDL) notified	LP*/SMP&C*		Not started		
Loss Prevention Notified	SMPQ&C		Not started		
Notification of Quality and Compliance; Pharmacy Leadership	RXTL*, PDL*, LP		Not started		
Notification of executive management	Pharmacy Leadership		Not started		
Loss notification: external					
Suspected loss form faxed to local DEA office	PDL, SMPQ&C		Not started		
Initial phone call of notification and suspected loss form faxed to OH Board of Pharmacy (OH stores only)	PDL, SMPQ&C		Not started		
Notification of local jurisdictional law enforcement (MD, PA, WV) (Document: Department notified, name of officer, and department phone number in the notes field.)	LP		Not started		Documentation:
Investigation					
Starting inventory date	PDL		Not started		
Date of inventory count of all controlled substances (closing inventory date)	RxTL, PDL		Not started		
Purchase and dispensing reports requested and received from Kayla Voelker	SMPQ&C		Not started		
Outdate/damage report requested and received from Greg Carlson	SMPQ&C		Not started		
Controlled drug audit completed	RxTL, PDL		Not started		
Reporting					
Discuss completion of DEA Form 106 with Risk/Legal and SMPQ&C	PDL		Not started		
DEA Form 106 completed online at www.deadiversion.usdoj.gov . (Print two copies.)	RxTL, PDL		Not started		
Copy of DEA Form 106 faxed to Risk/Legal, SMPQ&C, and LP	PDL		Not started		
Supplemental DEA Form 106 filed with DEA as necessary following approval from Risk/Legal and SMPQ&C	RxTL, PDL		Not started		
DEA Form 106 filed in Controlled Drug Records box	RxTL, PDL		Not started		
Investigation and reporting closed					
*					
District Loss Prevention Representative	LP				
Pharmacy Team Leader	RxTL				
Pharmacy District Leader	PDL				
Sr. Manager, Pharmacy Quality and Compliance	SMPQ&C				

GIANT EAGLE CONTROLLED SUBSTANCE LOSS PROCEDURE (2)

I. Date of suspected loss:

- Pharmacy TL notifies PDL and Sr. Manager, Pharmacy Quality and Compliance (SMPQ&C)
- Collect relevant documentation by PDL
- LP, Risk/Legal, and pharmacy leadership contacted by SMPQ&C

II. Within one business day of suspected loss:

- complete GE Suspected Controlled Substance Loss Form
- fax copy of notification form to DEA office and state board (for Ohio stores only)
- place phone call to local DEA office
- if OH location; place call to local OH Board of Pharmacy Agent
- fax GE Suspected Controlled Substance Loss form to GE offices (Pharmacy Quality & Compliance 412-968-1552; and Corporate Risk Management 412-967-3761)

II. Within 48 hours of suspected loss:

- PDL and LP visit pharmacy to assess situation, confirm or refute loss
- no loss identified; reiterate GE policies & procedures on handling of controls
- if loss is confirmed, begin investigation

III. Investigation

- PDL and LP will coordinate investigation (with appropriate State Board representative in OH).
- conduct appropriate investigation to identify any TMs involved
- PDL and LP will oversee physical inventory by RxTL of all controlled substances (C-II – C-V) in the pharmacy to establish an end date
- request Control Drug Audit Spreadsheet from corporate for all C-II – C-V drugs from last biannual inventory (May 1) or last physical inventory to the established end date
- PDL and LP will conduct the controlled substance audit (compare physical inventory to data on the Control Drug Audit Spreadsheet for all controlled substances.
- quantify identified loss(es).

IV. Reporting

- Immediately upon verifying loss of controlled substance(s); contact Pharmacy Quality & Compliance and Corporate Risk Management to discuss completion of DEA 106 form
- Pharmacy TL will submit DEA 106 online and print final copy for files.
- Pharmacy TL will fax copy of final submitted DEA 106 to GE offices (Pharmacy Quality & Compliance 412-968-1552; and Corporate Risk Management 412-967-3761)
- Supplemental 106 forms can be submitted if necessary
- Depending on the severity of the identified loss; pharmacy leadership will notify senior chain of command
- If TM involvement is identified and personnel decisions need to be made; LP will notify appropriate individual within Retail HR to determine impact on employment
- LP in PA, MD or WV locations owns contacting local jurisdictional law enforcement

	<h1>Receiving Controlled Drugs</h1>	Compliance
<p>Steps:</p>		
<ol style="list-style-type: none"> 1. Receive totes from delivery personnel. <p>NOTE: Courier delivery personnel are not permitted to enter the pharmacy.</p>		
<ol style="list-style-type: none"> 2. Verify the number of totes delivered matches the driver's delivery log. 		
<ol style="list-style-type: none"> 3. Sign the delivery log. 		
<ol style="list-style-type: none"> 4. Open the totes and remove all controlled drugs (CII – CV) from the totes and place in a designated location. <p>NOTE: McKesson and HBC totes have controlled drugs quarantined in white plastic bags. Anda deliveries have controlled drugs quarantined in separate containers.</p>		
<ol style="list-style-type: none"> 5. Check the controlled drugs received against the shipping list and/or invoice – must be completed by a pharmacist. <ul style="list-style-type: none"> • Circle the quantity on the shipping list/invoice for each controlled drug (CII-CV) drug and initial the corresponding line. • Sign with the full signature and date the invoice after verifying the order is correct. • When receiving CII drugs, complete the NDC, Quantity Received and Date Received on each line of the Form 222 and staple the form 222 to the invoice. • The pharmacist should exercise professional judgment to determine the appropriateness of the invoiced quantities. 		
<p>NOTE: HBC totes are shipped with a packing list, but invoices must be manually printed. McKesson and Anda shipments include both a packing list and an invoice.</p>		
<ol style="list-style-type: none"> 6. File all signed and dated invoices in chronological order in the Controlled Drug Records Box under the appropriate tabs. 7. Log all CII drugs into the perpetual inventory logbook – must be completed by a pharmacist. 8. Secure all CII drugs into the locked cabinet or safe – must be completed by a pharmacist. <ul style="list-style-type: none"> • All CII drugs must be locked in cabinets or safes • The key to the locked cabinets or safes must be in the pharmacists' physical possession at all times. • Only a pharmacist can access the locked CII storage cabinets or safe to retrieve and return CII medications. 9. Place all CIII – CV drugs in the appropriate place on the pharmacy inventory shelves. 		